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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/361,619	07/27/1999	SHEENA M. LOOSMORE	1038-921-MIS	5733

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EXAMINER
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ART UNIT	PAPER NUMBER
1645	16

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/361,619	Loosmore et al.
Examiner	**Art Unit**
S. Devi, Ph.D.	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 25, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10* is/~~are~~ pending in the application.

4a) Of the above, claim(s) *3 and 4* is/~~are~~ withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, and 5-10* is/~~are~~ rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicants' Amendment

1) Acknowledgment is made of Applicants' amendment filed 03/25/02 (paper no. 15) in response to the non-final Office Action mailed 09/25/01 (paper no. 14). With this, Applicants have amended the specification.

The Office appreciates the Applicants' supply of a copy of the pending or allowed claims from the pending applications, SN 08/483,855 and SN 08/945,567.

Status of Claims

2) Claims 11-23 have been canceled via the amendment filed 03/25/02.

Claims 1 and 3 have been amended via the amendment filed 03/25/02.

Claims 3 and 4 encompass non-elected nucleotide sequence species (SEQ ID NO: 12 and 5) and are currently withdrawn from consideration. These claims were by mistake included in the rejection statements in paragraphs 11 and 14 of the Office Action mailed 09/25/01. The Examiner regrets this error.

Claims 1-10 are pending.

Claims 1, 2 and 5-10 are currently under examination.

Prior Citation of Title 35 Sections

3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Maintained

5) The objection to the informal drawings made in paragraph 7 of the Office Action mailed 09/25/01 (paper no. 14) is maintained for reasons set forth therein. Applicants are asked to note the changes effected 03 May 2001, particularly the changes to the 'Timing of Corrections':

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

A. Correction of Informalities -- 37 C.F.R 1.85; 1097 O.G. 36

New formal drawings must be filed with the changes incorporated therein. The art unit number, application number (including series code) and number of drawing sheets should be written on the reverse side of the drawings. Applicant may delay filing of the new drawings until receipt of the "Notice of Allowability" (PTOL-37 or PTO-37). If delayed, the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" to avoid extension of time fees. Extensions of time may be obtained under the provisions of 37 C.F.R 1.136(a) for filing the corrected drawings (but not for payment of the issue fee). The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

B. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the three month shortened statutory period set in the "Notice of Allowability" (PTO-37). Within that three month period, two weeks should be allowed for review of the new drawings by the Office. If a correction is determined to be unacceptable by the Office, Applicant must arrange to have an acceptable correction re-submitted within the original three month period to avoid the necessity of obtaining an extension of time with extension fees. Therefore, applicant should file corrected drawings as soon as possible.

Failure to take corrective action within the set (or extended) period will result in ABANDONMENT of the application.

Objection(s) Withdrawn

6) The objection to the specification made in paragraph 9 of the Office Action mailed 09/25/01 (paper no. 14) is withdrawn in light of Applicants' amendment to the specification.

Rejection(s) Moot

7) The rejection of claim 3 made in paragraphs 11(a) and 11(c) of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 112, second paragraph, as being indefinite, is currently moot for the reasons provided above in paragraph 2.

8) The rejection of claims 3 and 4 made in paragraph 14 of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 5,808,024 - Applicants' IDS), is currently moot for the reasons provided above in paragraph 2.

Rejection(s) Withdrawn

9) The rejection of claim 1 made in paragraph 11(a) of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

10) The rejection of claim 2 made in paragraph 11(b) of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants contend that since "claim 1 refers specifically to strains 4223, Q8 and LES-1, there are excluded from the strains claimed in claim 2", and that strains listed in Table 1A not expressing a 200 kDa protein are not included.

Applicants' arguments have been carefully considered, but are non-persuasive. Claim 2 is still indefinite and confusing, because the claim as recited includes a nucleic acid molecule from each of the strain listed in Table 1A except 4223, Q8 and LES-1. This does not exclude strains RH408, 3, 56, M5, ATCC25240, Q-6, Q-9, Q12 and R-2. However, the expression of 200 kDa protein by these strains is indicated in the Table to be "-" and therefore, inclusion of these strains within the scope of the claim renders the claim language confusing and renders the metes and bounds of the claim indeterminate. Furthermore, the contents of Table 1A are subject to changes via amendments and such amendments to Table 1A would change the scope of claim

2.

11) The rejection of claim 9 made in paragraph 11(b) of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein and herebelow.

Applicants contend that the molecule has 'approximately' half the size of the full length protein and "is a C-terminal fragment". However, the specification, as originally filed, does not define what precise length of the recited protein is encompassed in this relative limitation, and therefore the metes and bounds of the claim is unclear.

12) The rejection of claims 7 and 8 made in paragraph 12 of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 112, first paragraph, as being non-enabled, with regard to the deposit issue, is maintained for reasons set forth therein and herebelow.

Applicants contend that the plasmid vectors, pKS348 and pKS294, have been deposited at the ATCC under the Budapest Treaty and that the specification describes how to produce plasmids pQWE and pQWF from pKS348. The attorney of record provides the statement stating that "all restrictions to public access to the deposits will be removed upon the grant of a patent on this application".

Applicants' arguments have been carefully considered and are partly persuasive. As set forth in bold letters in paragraph 12 of the Office Action mailed 09/25/01 (paper no. 14), the statement should state that all restrictions upon public access to the deposit will be "irrevocably" removed upon the grant of a patent on this application. Such a statement would overcome the rejection.

13) The rejection of claims 1, 2, 5, 6, 9 and 10 made in paragraph 14 of the Office Action mailed 09/25/01 (paper no. 14) under 35 U.S.C § 102(e) as being anticipated by Sasaki *et al.* (US 5,808,024 - Applicants' IDS), is maintained for reasons set forth therein and herebelow.

Applicants contend that

Applicants' arguments have been carefully considered, but are non-persuasive. Claim 1 does not exclude nucleic acid molecules of any particular strain(s) of *M. catarrhalis* and therefore encompass every strain of *M. catarrhalis*. Claim 1, part (a) does not include recitations, such as, a 'start codon' or an 'open reading frame'. Therefore, Sasaki *et al.* do not

have to identify any start codon or open reading frame in the sequence of their Figure 6 to meet the claim limitations in part (a) of claim 1. Claim 1, for example, includes an isolated and purified nucleic acid molecule 'having' (i.e., open claim language) a nucleotide sequence selected from one of the three Markush species, (a), (b) or (c). The transitional phrases "having", "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986)*; *In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981)*; and *Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948)* ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). As drafted currently, the Markush species recited in part (a) of the claim can be a complementary sequence, for example, to SEQ ID NO: 6. The limitation "complementary sequence thereto" encompasses a nucleotide sequence that is fully or partially complementary. A sequence with 20%, 60% or 90% sequence identity with SEQ ID NO: 6 would qualify as a 'complementary sequence'. In this regard, Sasaki's ('024) nucleotide sequence showing as high as 99.8% sequence identity (see the search report attachment provided along with the Office Action mailed 09/25/01) certainly qualifies as a complementary sequence to the instantly claimed SEQ ID NO: 6. Therefore, the nucleic acid molecule depicted in Figure 6 is complementary to the instantly claimed nucleotide sequence of SEQ ID NO: 6.

Furthermore, Sasaki's sequence also meets part (c) of claim 1. In order to meet the limitations in part (c) of claim 1, the prior art reference does not have to expressly identify any start codon or open reading frame in the nucleotide sequence. However, the brief description for Figure 6 states that the nucleotide sequence of the gene shown in Figure 6 has an open reading frame of the about 200 kDa outer membrane protein of *M. catarrhalis*. See lines 30-32 and 59-62 in column 6. Further, since the instant specification does not define or describe what is encompassed in the limitation "about 80 to 90 bp", this limitation is interpreted broadly. That the ATG codon is present in the Sasaki's ('024) nucleotide sequence and is about 102 bp (i.e.,

about 90) upstream of the tract of three consecutive GGG nucleotides is inherently evident or self-explanatory from Figure 6 of the '024 patent. See the attached Figure 6 of Sasaki *et al.* with the ATG and GGG nucleotides boxed and highlighted in yellow. The rejection stands.

Double Patenting Rejection

14) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

Claims 1, 2, 5, 6, 9 and 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 14-23 of the co-pending application, SN 08/945,567. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the overlapping scope between the instantly claimed nucleic acid and the nucleic acid molecule having the DNA sequence of SEQ ID NO: 2 and 3, a vector and a host cell comprising the same of the pending application.

Rejection(s) under 35 U.S.C. § 112, First Paragraph

15) Claims 1, 2 and 5-10 are rejected under 35 U.S.C § 112, first paragraph, because the specification while being enabling for an isolated and purified nucleic acid molecule having a nucleotide sequence as recited in part (c) of claim 1 which encodes a 200 kDa outer membrane protein from certain strains of *M. catarrhalis,* for example, strains 4223, LES-1 and Q8, does not

reasonably provide enablement for such a molecule from every strain of *M. catarrhalis* encompassed in Table 1A other than 4223, Q8 and LES-1, as claimed in a broad sense.

Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

In the instant case, it is evident from the results shown in Table 5 that there is no certainty or guarantee that every strain of *M. catarrhalis* that is able to express the 200 kDa outer membrane protein contains a gene or nucleotide sequence that is characterized by 3, or a multiple of 3 consecutive G nucleotides and an ATG start codon as recited in part (c) of claim 1. For instance, Table 5 shows that at least three strains of *M. catarrhalis* that were analysed did express the 200 kDa outer membrane protein, yet had 10 (i.e., not a multiple of 3) G nucleotides in the G tract of the gene and a 'possible' GTG start codon. The specification in the second full paragraph on page 42 of the instant specification describes that Table 5 represents the results obtained with 24 other strains of *M. catarrhalis*. Table 5 depicts that 18 of these 24 strains were producers of the 200 kDa protein, of which three did not have 3 or a multiple of 3 G nucleotides in the G tract of the gene and did not have GTG as the possible start codon. Table 1A that is recited in claim 2 lists much more than 24 strains of *M. catarrhalis*, about 79 of which are indicated in the right column of the Table to be expressers of the 200 kDa protein. The nucleotide sequences of all these 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A, except 4223, Q8 and LES-1, are encompassed in the scope of the claims, all of which are required to have a G tract of 3 or a multiple of 3 consecutive G nucleotides and an ATG start codon about 80 to 90 bp upstream of the G tract as recited in part(c) of claim 1, from which claim 2 depends. However, there is no evidence within the instant specification that all these about seventy nine 200 kDa protein-expressing strains of *M. catarrhalis* from Table 1A do indeed carry a nucleotide sequence

with the recited structural properties. There is no evidence that nucleic acid molecules from all these strains having nucleotide sequences with such structural characteristics were indeed isolated, purified and genetically analysed and that Applicants had possession of such sequences at the time of the invention. This is critical in light of the unpredictability evident from the results depicted Table 5 representing 18 strains of *M. catarrhalis* that produced the 200 kDa protein. The full scope of the instant claims is viewed as being non-enabled. Since the observation obtained from the genetic analysis regard of one strain of *M. catarrhalis* that expresses the 200 kDa protein cannot be extrapolated to every other 200 kDa protein-expressing strain of *M. catarrhalis*, undue experimentation would have been required. Due to the lack of evidence, the lack of specific guidance, the breadth of the claims, the lack of working examples enabling the full scope, the demonstrated unpredictability factor and the quantity of experimentation necessary, undue experimentation would have been required by one of ordinary skill in the art to reproducibly practice the full scope of the invention.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

16) Claims 1, 2 and 5-10 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 1 is indefinite in the recitation "another strain". It is unclear why the recitation 'another strain' is used in the claim as opposed to 'a strain'. The term 'another' strain is usually used either in comparison with or with the exclusion of one other strain. In the instant case, without the recitation or identification of the other strain, the limitation 'another strain' renders the claim vague and/or confusing.

(b) Claims 2 and 5-10, which depend directly or indirectly from claim 1, are also rejected as being indefinite because of the vagueness or indefiniteness identified above in claim 1.

Rejection(s) under 35 U.S.C § 102

17) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18) Claims 1, 5-7, 9 and 10 are rejected under 35 U.S.C § 102(e) as being anticipated by Loosmore *et al.* (US 6,391,313, filed 15 July 1999) ('313).

Loosmore *et al.* ('313) teach the pKS348 plasmid vector identical to the one shown in Figure 10 of the instant application. *E. coli* host cells transformed with the pKS348 plasmid vector are taught. See Figure 14B of patent '313 and column 16. The prior art plasmid would inherently contain the nucleic acid molecule of claim 1.

Claims 1, 5-7, 9 and 10 are anticipated by Loosmore *et al.* ('313).

19) Claims 1, 5, 6, 9 and 10 are rejected under 35 U.S.C § 102(b) as being anticipated by Sasaki *et al.* (WO 96/34960 - Applicants' IDS) ('960).

It is noted that the limitation "complementary sequence thereto" in part (a) of claim 1 encompasses nucleotide sequences that are fully or partially complementary, and therefore includes nucleotide sequences that are 20%, 60% or 99% identical to SEQ ID NO: 6.

Sasaki *et al.* ('960) disclose an isolated and purified nucleic acid molecule having a nucleotide sequence encoding a 200 kD outer membrane protein of a strain of *M. catarrhalis* (see claims 14-23 and Figure 6). A sequence search performed in the Office for the nucleotide sequence of SEQ ID NO: 6 indicated that the prior art sequence has 99.8% sequence identity (see the attached sequence search report). Therefore, the prior art nucleotide sequence is complementary to the claimed nucleotide sequence of SEQ ID NO: 6. A plasmid or an expression vector for transforming a host comprising the nucleic acid molecule wherein the host cell is *E. coli* is taught (see abstract; page 28; and claims 14-23).

Claims 1, 5, 6, 9 and 10 are anticipated by Sasaki *et al.* ('960).

Relevant Prior Art

20) The prior art made of record and not relied upon currently in any of the rejections is considered pertinent to Applicants' disclosure:

- Sasaki *et al.* (*In*: *Abstracts of the American Society for Microbiology*, Chicago, Illinois, USA, vol. 99, page 89, abstract B/D-306, 30 May - 03 June 1999, abstract - Applicants' IDS) (Sasaki *et al.*, 1999) teach a cloned or PCR-amplified gene (i.e., a nucleic acid molecule)

encoding a 200 kD protein of *M. catarrhalis* which is characterized by a G tract wherein the number of Gs present is nine (i.e., a multiple of 3).

- Sasaki *et al.* (US 6,335,018, filed 01 May 1995) ('018) disclose an isolated and purified nucleic acid molecule having a nucleotide sequence encoding a 200 kD outer membrane protein of a strain of *M. catarrhalis*, a plasmid, an expression vector and a host cell comprising the same (see entire document, especially abstract and Figure 6).

Remarks

21) Claims 1, 2, 5-10 stand rejected.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

June, 2002

S. DEVI, PH.D.
PRIMARY EXAMINER